

98N-607-001

December 20, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 98N-607: Proposed Rule; General Requirements for Blood, Blood Components, and Blood Derivatives; Notification of Deferred Donors

To Whom It May Concern:

The American Association of Blood Banks (AABB) is the professional association for approximately 2200 institutions engaged in the collection and transfusion of blood and blood products, including all American Red Cross blood services regions, independent community blood centers, hospital-based blood banks and transfusion services, and more than 8500 individuals engaged in all aspects of blood collection, processing and transfusion. Our members are responsible for virtually all of the blood collected and more than eighty percent of the blood transfused in this country. The AABB's highest priority is to maintain and enhance the safety of the nation's blood supply. The AABB appreciates the opportunity to comments on the Food and Drug Administration's (FDA) proposed rule on the general requirements for blood, blood components, and blood derivatives; notification of deferred donors.

The FDA states that the focus of this proposed rule is "to require donor notification when the donor is deferred due to testing results or failure to meet donor suitability criteria, and to provide the reason for the deferral." The AABB believes that blood banks have an ethical obligation to notify donors of any medically significant abnormality detected during the predonation evaluation or as a result of laboratory testing. In fact, the AABB *Standards for Blood Banks and Transfusion Services* has required such notification since 1976. The FDA acknowledges in the supplementary information of this proposed rule, Section II, that the industry has already implemented past FDA guidance recommendations and developed their own guidance on donor notification.

However, this proposed rule goes far beyond the stated focus. Despite our commitment to donor notification, the AABB is most concerned about codifying details of notification into regulation. One of the FDA stated reasons for this proposal is to provide FDA with clear enforcement authority if compliance problems occur. We believe that this enforcement authority can be established by simply requiring notification

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as stated in the proposed 630.6 (a) and that defining specifics of the notification in 640.6(b) is not only unnecessary, but unwarranted.

General comments

- **606.160(x)** requires record of the donor's permanent address.

The term permanent address should be clarified. While we understand the need for an address at which the donor can be contacted, this may not always be identical to a permanent address. For example, students have an address at which they currently reside, but their home address is usually considered the permanent address. We believe that the address where the person is currently living is sufficient. We understand that requiring a permanent address has been a requirement for the plasma collection industry for some time and believe that this is an attempt to make the requirements uniform. We do not believe it is necessary to obtain any address other than the one the donor supplies during donor registration.

- **630.6 (b)**

The exact content of the notification message should not be codified. We suggest the FDA adopt the language of the AABB *Standards for Blood Banks and Transfusion Services*. Standard B3.500 states that "The medical director shall establish the means to notify donors of any medically significant abnormality detected during the predonation evaluation or as a result of laboratory testing. Appropriate education, counseling, or referral shall be offered." This Standard indicates the types of information, which should be included in the notification, but does not dictate specific content.

- **630.6 (c)**

There is no reason to require three attempts at notification within eight weeks. If deferral is necessary, it will be known within a short period of time following the donation, and any mail is likely to be within the forwarding period, even if the donor has moved. These donor notifications do not warrant the same requirements as patient lookback notifications, which may occur, distant in time to the precipitating event. One attempt at notification should be sufficient. Repeating the same notification mechanism three times is unlikely to increase the yield. Multiple methods of notification are likely to be more effective, and should be left to the individual blood establishment to determine. Documentation should be acceptable if there is a record that the blood collection facility sent a letter, which was not returned by the Postal Service, or a record that some other type of notification was done. Documentation should not require the use of certified mail, return receipt requested.

The AABB supports notification of deferral due to donor suitability issues at the time of the attempted donation. Documentation of deferral in the donor record should be sufficient. Such deferrals should not require any additional notifications.

FDA specifically requested comments on whether to require notification of autologous donors of repeatedly reactive and supplemental test results even though such donors would not be deferred.

The AABB believes that autologous donors should be notified of repeatedly reactive test results. Further, as we indicated in our comments to the proposed rule on Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents, Docket No. 98N-051, we believe that such donors should be deferred as allogeneic donors. Two of the stated reasons this rule is being proposed are “so that donors may be informed of their deferral and seek medical counseling or treatment if appropriate, and “precautions taken to minimize the risk of transmissions by informed donors may reduce the spread of communicable diseases in the population.” These reasons are equally applicable to both autologous and allogeneic donors. Another stated reason, “to improve blood safety by preventing re-donation by individuals at risk.” also applies to autologous donors, some of whom may wish to become allogeneic donors in the future. Notification of autologous donors of the results of infectious disease testing is widely practiced already and would not impose any significant new burdens on most donor centers or transfusion services.

FDA specifically requested comments on whether to notify donors who test repeatedly reactive for HTLV types I and II and anti HBc on only one occasion or wait to notify donors upon testing repeatedly reactive the second time.


The AABB supports donor notification at the time of actual donor deferral. The primary purpose of donor notification is to alert the donor that they are no longer eligible to donate and the donor remains eligible unless they have tested repeatedly reactive on a second occasion. The FDA has recognized that there is a concern with HTLV testing by permitting the use of a dual EIA strategy. Because the rate of false positive tests is high, there is no medical significance the first time the donor tests repeatedly reactive. Notification at this point serves no useful purpose.

FDA requested comments on (1) the methods of notification that would help assure adequate donor confidentiality and (2) the current application and sufficiency of Federal, State, and local laws that protect the privacy of the individuals being notified.

The actual method of notification and the contents of the notification should not be codified. The exact mechanism should be left to the blood center to determine. A successful means of notification in one part of the country may be less than optimal in other areas. While use of certified mail may be one way of attempting to ensure donor confidentiality, it may actually be counter productive since it is known that some donors deliberately do not open such mail.

Once again, the AABB appreciates the opportunity to comments on the proposed rule. If you have any questions, please contact Kay R. Gregory, AABB's Director of Regulatory Affairs at 301-215-6590 or by e-mail at kayg@aabb.org.

Sincerely,


Paul M. Noss, MD
President